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**Sent:** 6/3/2011 2:16:13 PM  
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**Subject:** NEWS UPDATES: Despite Industry Concern, EPA Advancing Methanol Noncancer Risk Study (Inside EPA)

## Despite Industry Concern, EPA Advancing Methanol Noncancer Risk Study

Posted: June 1, 2011

EPA appears to be pressing ahead with its schedule for its assessment of methanol's noncancer risks, despite concerns from industry that the agency's draft report is overly stringent and does not include the latest research on the chemical.

Methanol industry representatives urged agency staff at a May 26 listening session to delay the assessment until they can review a series of studies published by a Canadian professor and funded by the Methanol Foundation. The new research "raises fundamental questions about the choice of the point of departure for any quantitative assessment of methanol and the designation of reference doses," said Chuck Elkins, a consultant to the Methanol Institute, the group that represents producers and users of the substance. *Relevant documents are available on InsideEPA.com. (Doc ID: [2365333](#))*

However, an agency source indicates that EPA is unlikely to delay the assessment.

And Elkins and Gregory Dolan, the institute's executive director, said that EPA staff told them during a meeting with research chief Paul Anastas last month that the agency will proceed with the schedule as planned and are looking at a date for the peer review meeting in late June or July.

In response to questions at the meeting, Dolan said that EPA staff told him they are reviewing the industry-funded research and will discuss their impression of it to the peer review panel. But the

agency source indicates that a decision may not have been made on whether to do that.

Methanol is a chemical widely used in the production of alternative and renewable fuels, paints, plastics, solvents and textiles. EPA says it anticipates increased demand for methanol, which it says is "growing steadily in almost all end uses," but is largely linked to increased biodiesel production.

EPA's draft assessment of methanol has long been controversial over its first time listing of the chemical as a likely carcinogen and its first-time safe daily dose for inhalation exposure, or reference concentration (RfC), of 2 milligrams per cubic meter of air.

But the draft assessment of methanol has already been delayed nearly a year while agency officials grapple with how to handle data from a controversial Italian lab that was the basis of its cancer risk assessment. Industry protested the use of the Ramazzini Institute data, arguing that its protocol was unconventional and overstated cancer risk, leading EPA to calculate an overly stringent assessment of the chemical's cancer risks. "Getting this done right is critically important to the U.S. and the world economy," Dolan said, noting that the chemical and its downstream uses "create thousands of jobs across the U.S. economy with total economic impact of \$3.5 billion dollars per year."

Following a review last spring of a selection of the Ramazzini lab's methanol slides by National Toxicology Program (NTP) pathologists, EPA pulled two finalized Integrated Risk Information System assessments and paused four pending assessments -- including methanol -- while it considered how to handle the situation.

EPA is awaiting the results of an expanded NTP review of Ramazzini data, which an industry source says could be completed next month.

But even as EPA awaits the pathology review, the agency recently announced that it has decided to move forward on the noncancer portion of the methanol assessment. But industry is protesting the agency's decision to advance that portion of the assessment without updating it with the industry-funded research.

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